



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-1129]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; National Agriculture and Food Defense Strategy Survey

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting “Currently under Review - Open for Public Comments” or by using the search function. The OMB control number for this information collection is 0910-0855. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-7726, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

National Agriculture and Food Defense Strategy Survey

OMB Control Number 0910-0855--Extension

We are seeking OMB approval of the National Agriculture and Food Defense Strategy (NAFDS) under section 108 of the FDA Food and Safety Modernization Act (FSMA). This is a voluntary survey of State, local, territorial, and/or tribal (SLTT) governments intended to gauge government activities in food and agriculture defense from intentional contamination and emerging threats. The collected information will be included in the mandatory NAFDS followup Report to Congress. The authority for us to collect the information derives from the Commissioner of Food and Drugs' authority provided in section 1003(d)(2)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393(d)(2)(C)).

Protecting the nation's food and agriculture supply against intentional contamination and other emerging threats is an important responsibility shared by SLTT governments as well as private sector partners. On January 4, 2011, the President signed into law FSMA. FSMA focuses on ensuring the safety of the U.S. food supply by shifting the efforts of Federal regulators from response to prevention and recognizes the importance of strengthening existing collaboration among all stakeholders to achieve common public health and security goals. FSMA identifies some key priorities for working with partners in areas such as reliance on Federal, State, and local agencies for inspections; improving foodborne illness surveillance; and leveraging and enhancing State and local food safety and defense capacities. Section 108 of FSMA (NAFDS) requires the Department of Health and Human Services (HHS) and the U.S. Department of Agriculture (USDA), in coordination with the Department of Homeland Security (DHS), to work together with State, local, territorial, and tribal governments to monitor and measure progress in food defense.

In 2015, the initial NAFDS Report to Congress detailed the specific Federal response to food and agriculture defense goals, objectives, key initiatives, and activities that HHS, USDA, DHS, and other stakeholders planned to accomplish to meet the objectives outlined in FSMA.

The NAFDS charts a direction for how Federal Agencies, in cooperation with SLTT governments and private sector partners, protect the nation's food supply against intentional contamination. Not later than 4 years after the initial NAFDS Report to Congress (2015), and every 4 years thereafter (i.e., 2019, 2023, 2027, etc.), HHS, USDA, and DHS are required to revise and submit an updated report to the relevant committees of Congress.

FDA is the Agency primarily responsible for obtaining the information from Federal and SLTT partners to complete the NAFDS Report to Congress. An interagency working group will conduct the survey and collect and update the NAFDS as directed by FSMA, including developing metrics and measuring progress for the evaluation process.

The survey of Federal and State partners will be used to determine what food defense activities, if any, Federal and/or SLTT agencies have completed (or are planning on completing) from 2021 to 2025. Planning for the local, territorial, and tribal information collections will commence during this period of renewal. The survey will continue to be repeated approximately every 2 to 4 years, as described in section 108 of FSMA. The NAFDS survey is being administered for the purpose of monitoring progress in food and agricultural defense by government agencies.

A purposive sampling strategy is employed, such that the government agencies participating in food and agricultural defense are asked to respond to the voluntary survey. Food defense leaders responsible for conducting food defense activities during a food emergency for their jurisdiction are identified and will receive an emailed invitation to complete the survey online; they will be provided with a web link to the survey. The survey will be conducted electronically on the FDA.gov web portal, and results will be analyzed by the interagency working group.

Description of Respondents: Respondents to this collection are SLTT government representatives (survey respondents) who are food defense leaders responsible for conducting food defense activities during a food emergency for their jurisdictions.

In the *Federal Register* of January 4, 2021 (86 FR 104), FDA published a 60-day notice requesting public comment on the proposed collection of information. Although one comment was received, it was not responsive to the four collection of information topics solicited and therefore will not be discussed in this document.

We estimate the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden¹

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
SLTT Surveys	500	1	500	0.33 (20 minutes)	165

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

The FDA Office of Partnerships reviewed the questionnaire and provided the estimate of time to complete the survey. The total burden is based on our previous experiences conducting surveys. The burden has been revised to reflect the total number of States and possible number of local, tribal, and territorial entities that may partake of the survey. Based on a review of the information collection since our last request for OMB approval, we have increased our burden estimate by 149 hours (from 16.17 to 165 hours) and 451 respondents (from 49 to 500 respondents).

Dated: June 7, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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